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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/094,921	06/15/1998	HORST LINDHOFFER	80309	9008

7590

06/17/2004

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EXAMINER
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HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/094,921	<b>Applicant(s)</b> LINDHOFER ET AL.	
	<b>Examiner</b> Anne Holleran	<b>Art Unit</b> 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 13-21, 23 and 26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 13-21, 23 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. The amendment filed on Feb. 24, 2004 is acknowledged. Claim 27 was canceled.
2. Claims 1-8, 13-21, 23, and 26 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The declaration of Horst Lindhofer filed under 37 C.F.R. 1.132 has been considered.

***Claim Rejections Withdrawn:***

5. The rejection of claims 1-8, 13, 15, 16, 19-21, 23, 26 and 27 under 35 U.S.C. 103(a) as being unpatentable over Volker et al (U.S. Patent 5,911,987; issued June 15, 1999; 102(e) date Feb. 21, 1997) in view of Deo et al (U.S. Patent 5,837,243; issued Nov. 17, 1998; filed June 7, 1996) and further in view of Lindhofer et al (Lindhofer, H. et al, J. Immunology, 155: 219-225, 1995) is withdrawn in view of the amendment to claim 1 and in view of the declaration of Horst Lindhofer.

6. The rejection of claims 1, 14, 17 and 18 under 35 U.S.C. 103(a) as being unpatentable over Volker (supra) in combination with Deo, in view of Honsik (U.S. Patent 4,844,893; published July 4, 1989) and further in view of Lindhofer (supra) is withdrawn in view of the amendment to claim 1 and in view of the declaration of Horst Lindhofer.

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***New Grounds of Rejection:******Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 23 and 26 are directed to an invention not patentably distinct from claims 1-13 of commonly assigned U.S. Patent 6,551,592. Specifically, claim 23 is directed to a method of treatment comprising the administration of a preparation prepared according to claim 1, which a preparation comprising inactivated tumor cells and bispecific antibodies with the same characteristics as those of recited in the method claim 1 of commonly assigned U.S. Patent 6,551,592. Claim 26 is interpreted as reading on a preparation comprising inactivated tumor cells and bispecific antibodies with the same characteristics as those recited in the method of claim 1 of commonly assigned U.S. Patent 6,551,592.

Claims 23 and 26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,551,592 in view of Volker (U.S. Patent 5,911,987). Claims 1-13 are drawn to methods of treatment of a human or animal subject consisting of administering to the subject intact heterologous bispecific antibodies, where the heterologous bispecific antibodies have the same characteristics as those in

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the methods of claims 23 and 26. Volker teaches methods comprising the administration of tumor cells armed with bispecific antibodies for the purpose of increasing the chance that immune cells will come into contact with the tumor cells. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have altered the methods of treatment of U.S. Patent 6,551,592 to include the administration of inactivated tumor cells as taught by Volker to make the methods and pharmaceutical preparations of claims 23 and 26.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned 6,552,592, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

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8. Claims 1-8, 13-21, 23 and 26 are directed to an invention not patentably distinct from claims 1, 7, 10, 19, 22 and 23 of commonly assigned U.S. Application 10/378,218. Specifically, the methods of claims 1, 7, 10, 19, 22 and 23 encompass the claimed methods and make obvious the pharmaceutical composition of claim 26.

Claims 1-8, 13-21, 23 and 26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7, 10, 19, 22 and 23 of copending Application No. 10/378,218. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed inventions of copending application No. 10/378,218 read on the methods and pharmaceutical compositions of the "use" claims 1-8, 13-21, 23 and 26, and because a preferred embodiment of the methods of claims 1, 7, 10, 19, 22 and 23 of copending Application NO. 10/378,218 is the same invention as that of "use" claims 1-8, 13-21, 23 and 26.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned 6,552,592, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was

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made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

9. Claims 23 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23 and 26 are indefinite because they refer to "a tumor cell preparation prepared according to the method of claim 1" or "a tumor cell preparation obtained by the method of claim 1". It is not clear if these claims are referring to the tumor cell preparation that is mentioned in the claims, i.e. an inactivated tumor cell sample, or to a preparation that comprises a mixture of bispecific antibodies with tumor cells. This rejection would be overcome if phrase "tumor cell preparation" were to be replaced with the phrase "antibody-tumor cell preparation".

10. Claims 23 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Hanna, Jr. (U.S. Patent 5,484,596; issued Jan. 16, 1996).

Claims 23 and 26 may be interpreted as reading on pharmaceutical compositions comprising, and methods of treatment comprising the use of, tumor cell preparations prepared according to the method of claim 1. Claim 1 refers to isolating autologous tumor cells and

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treating the tumor cells to prevent the survival following reinfusion. The specification teaches that one method of treating tumor cells to prevent their survival following reinfusion is irradiation.

Hanna, Jr. teaches methods comprising removing tumor tissue from a human cancer patient and treating the tumor tissue to obtain tumor cells and irradiating the tumor cells to be viable but non-tumorigenic ("viable but non-tumorigenic" is interpreted to read on cells that will not survive to create tumors following reinfusion). Hanna, Jr. teaches vaccines comprising the treated and non-tumorigenic tumor cells. Therefore, Hanna, Jr. teaches methods of treatment and pharmaceutical compositions that are the same as that claimed.

### ***Conclusion***


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (571) 272-0841.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran  
Patent Examiner  
June 9, 2004

  
**ALANA M. HARRIS, PH.D.**  
**PRIMARY EXAMINER**  
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